

**JAN 3 2006**

510(k) Number: K052119

Date: \_\_\_\_\_

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## **510(k) Summary**

### **Introduction**

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

### **510(k) Applicant**

Mammendorfer Institut für Physik und Medizin GmbH  
Oskar-von-Miller-Strasse 6  
82291 Mammendorf, Germany

### **510(k) Correspondent**

Robert N. Clark, President and Senior Consultant  
Medical Device Regulatory Advisors  
13605 West 7<sup>th</sup> Ave., Golden, CO USA  
Tel: 303-234-9412 / Fax: 303-234-9413

### **Date Prepared**

July 20, 2005

### **Trade Name of Device**

Tesla Guard<sup>®</sup>

### **Common Name of Device**

Patient Monitor

### **Classification Name**

Monitor, Physiological, Patient (without arrhythmia detector or alarms)

### **510(k) Classification**

21CFR§870.2300 / Class II  
Product Code: MWI

### **Device Description and Intended Use**

The Tesla Guard<sup>®</sup> design allows examination of intensive care patients while in an MRI-scanner. The Tesla Guard<sup>®</sup> construction, fiber optic finger probe, and additional shielding make it possible to use the device within the magnetic and RF fields of the MRI examination room. During use, the unit must be positioned in a way that the maximum field strength is not higher than 20 mT, and the distance to the magnet core is at least 1.5m.

## **Predicate Devices**

Infinity Gamma XL manufactured by Dräger Medical Systems Inc. (K033600, K030313, K017016, K990563, K983632)

## **Safety & Effectiveness**

### **Safety Testing**

The Tesla Guard complies with the Safety Testing requirements of EN 60601-1 (IEC 601-1).

### **EMC Compliance**

The Tesla Guard complies with the EMC requirements of standard EN 60601-1-2.

### **Biocompatibility**

The patient contact portions of the Tesla Guard fiber optic finger probe comply with the biocompatibility requirements of standard ISO 10993-1.

### **Verification and Validation**

Testing was completed to determine the influence of the Tesla Guard on the MRI system, and the influence of the MRI system on the Tesla Guard®.

Function and accuracy of the Tesla Guard was tested in both normal environment (Non MRI) and in MRI environment.

### **Laboratory Testing**

Laboratory testing using human subjects was conducted to validate the functional and accuracy specifications of the pulse oximeter fiberoptic sensors, and to demonstrate equivalency to the predicate device.

## **Risk Management**

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in MRI procedures, and must be familiar with all labeling and instructions for use associated with the device.

Mammendorfer Institut für Physik und Medizin GmbH believes that the Tesla Guard® is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.



JAN 3 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mammendorfer Institute for Physics and  
Medicine GmbH  
c/o Mr. Robert Clark  
President  
Medical Device Regulatory Advisors  
13605 West 7<sup>th</sup> Ave.  
Golden, CO 80401-4604

Re: K052119

Trade Name: Tesla<sup>Guard</sup>®

Regulation Number: 21 CFR 870.2300

Regulation Name: Cardiac Monitor (including cardiometer and rate alarm)

Regulatory Class: Class II (two)

Product Code: MWI

Dated: November 29, 2005

Received: December 01, 2005

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

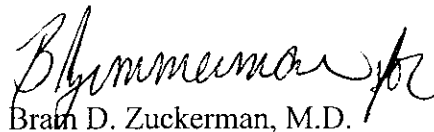
Page 2 – Mr. Robert Clark

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman", with a stylized flourish at the end.

Brian D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052119

Device Name: *Tesla<sup>Guard</sup>®*

### Indications For Use:

The *Tesla<sup>Guard</sup>®* Patient Monitor is capable of monitoring:

- SpO2 (Arterial Oxygen Saturation)
- ECG (3-Lead)
- IBP (Invasive Blood Pressure)
- NIBP (Non-invasive Blood Pressure)

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated based upon their professional assessment of the patient's medical condition.

The device is intended for use in the Adult, Pediatric and Neonatal populations.

### MRI Compatibility Statement:

The *Tesla<sup>Guard</sup>®* Patient Monitor is designed for use in an MRI-environment at a maximum magnetic field strength of 20mT.

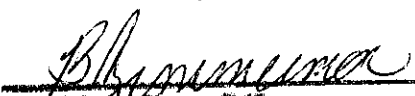
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number   K052119  

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